

Figures

FOUO "SECRET"

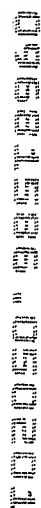
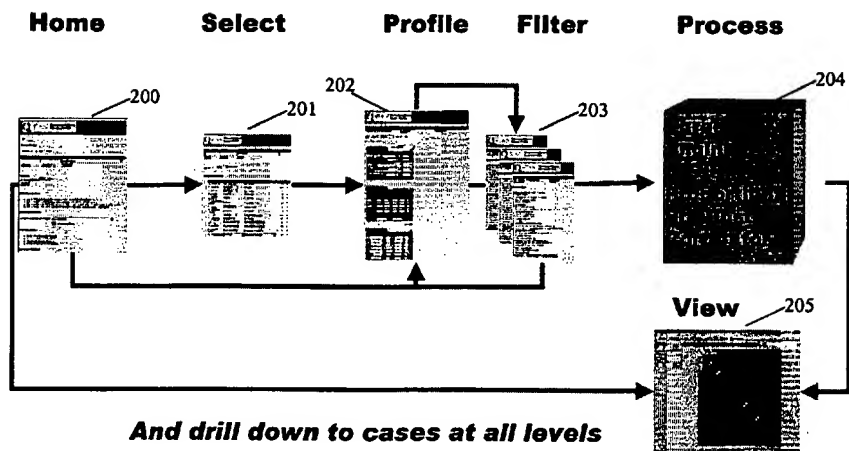
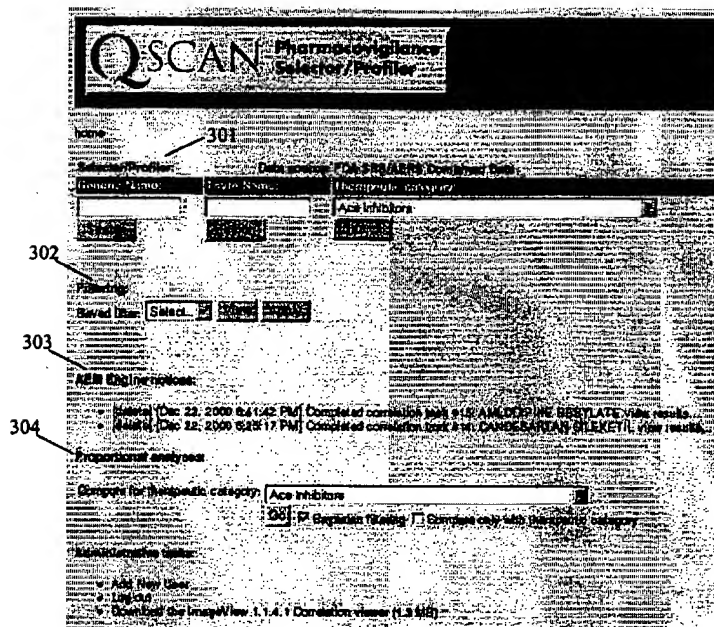
[illegible]

Figure 2



09631396-050201
T02050-08578950

Figure 3



0961586-05001



Downloaded from <http://ajphaphysoc.org/> at University of California, San Diego on November 11, 2014

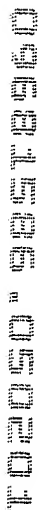


Figure 6

600	601	602	603	604	605	606	607
Map To	Verbatim	Source	Incidents	Case Count	OEDRx Processing	Cross-reference	First/Last Reported Reactions
PROZAC	PROZAC	SRS	47953	47937		Orange Book	Apr 27 1989/Dec 2 1997
PROZAC	Prozac	AERS	3378	3308	S	Orange Book	Nov 1 1997/Jun 29 1999
FLUOXETINE	FLUOXETINE HYDROCHLORIDE	SRS	2204	2203		NDCD Tradename	Jan 1 1979/Oct 14 1997
FLUOXETINE	Fluoxetine	AERS	574	571	S	NDCD Tradename	Nov 1 1997/Jun 18 1999
PROZAC	Prozac (Fluoxetine Hydrochloride)	AERS	379	378		M Orange Book	Nov 1 1997/Jun 12 1999
PROZAC	Prozac (Fluoxetine)	AERS	140	140		M Orange Book	Nov 1 1997/Apr 24 1999
FLUOXETINE	Fluoxetine Hydrochloride	AERS	122	122	S	Orange Book	Nov 14 1997/Jun 27 1999
FLUOXETINE	Fluoxetine (Fluoxetine Hydrochloride)	AERS	65	65		M Orange Book	Mar 1 1998/Jun 24 1999
FLUOXETINE	Fluoxetine Hcl	AERS	34	34		Orange Book	Nov 1 1997/Nov 1 1998
PROZAC	Prozac (Fluoxetine Hcl)	AERS	20	20		M Orange Book	Nov 1 1997/Mar 12 1999
PROZAC	Prozac (Fluoxetine Hydrochloride)	AERS	17	17		M Orange Book	
FLUOXETINE	Fluoxetine (Fluoxetine)	AERS	15	15		M Orange Book	Nov 15 1997/Jun 9 1999

T02050"925T2950

Figure 7

700

701

702

703

704

Reactions		
View: HLT (256 of 1495) filter		
Top 10 HLTs of 256	Reaction Count	% of Reactions
Hypertension and Increased blood pressure NEC	68	3.88%
General symptoms and signs NEC	57	3.25%
Disturbances in consciousness	52	2.97%
Renal function analyses	46	2.63%
Headaches NEC	46	2.63%
Cardiac function diagnostic procedures	46	2.63%
Neurological signs and symptoms NEC	45	2.57%
Nausea and vomiting (all forms)	43	2.45%
Asthenic conditions	43	2.45%
Vascular tests NEC including blood pressure	42	2.40%
Top 10 HLTs	488	Total reactions 1752

more details

102050 9857850

Figure 8

Concomitant Drugs

801

802

filter

801

		Non-				Total	%
		Suspect suspect					
Top 10 drugs		S	NS	S	NS	Total	%
HYDROCHLOROTHIAZIDE		9	36	0	0	45	10.79%
ASPIRIN		2	38	0	5	45	10.79%
FUROSEMIDE		2	32	0	1	35	8.39%
DIGOXIN		0	30	0	0	30	7.19%
AMLODIPINE BESYLATE		0	24	4	0	28	6.71%
ENALAPRIL MALEATE		4	15	0	5	24	5.76%
VERAPAMIL HYDROCHLORIDE		11	10	0	2	23	5.52%
ESTROGENS, CONJUGATED		0	23	0	0	23	5.52%
METOPROLOL SUCCINATE		8	11	0	3	22	5.28%
METOPROLOL TARTRATE		0	15	0	7	22	5.28%

Non-
Suspect suspect

Total Total Total

172

1141

1313

more details

102050" 92313960

Figure 9

900

Demographics

901

filter

Age Group	Male	Female	Unknown	Total	%
>75	18	73	0	91	21.82%
51-75	89	123	1	213	51.08%
31-50	30	16	0	46	11.03%
16-30	2	1	0	3	0.72%
<16	0	0	0	0	0.00%
Unknown	11	30	23	64	15.35%
Total	150	243	24	417	
%	35.97%	58.27%	5.76%		

more details

0954136-051204

Figure 10

1000 1001 1002

Report Dates filter

Timeframe	Count	%
1990-1999	446	100.00%
Total Report Dates		446

more details...

09681586 "050201
T02050" 985T8960

Figure 11

Outcomes			filter
Outcome	Count	%	
DEATH	36	7.19%	
DISABILITY	18	3.59%	
HOSPITALIZATION - INITIAL OR PROLONGED	231	46.11%	
LIFE-THREATENING	46	9.18%	
OTHER	168	33.53%	
REQUIRED INTERVENTION TO PREVENT PERMANENT IMPAIRMENT/DAMAGE	2	0.40%	
Total serious outcomes	333		
Total non-serious outcomes	168		
Total outcomes	501		

more details

09621586 "050201

Figure 12

102050 " 92512950

Reactions | Drugs | Outcomes | Report Sources | Timeframes | Demographics | Cases | Filter Notes

Deafness

Reactions

- ☒ blood and lymphatic system disorders
- ☒ cardiac disorders
- ☒ congenital and familial genetic disorders
- ☒ ear and labyrinth disorders
- ☒ external ear disorders (exc congenital)
- ☒ hearing disorders
- ☒ deafness and hyperacusis
- ☒ deafness conductive (exc otosclerosis)
- ☒ deafness hyposensory
- ☒ deafness permanent
- ☒ deafness transitory
- ☒ dysacusis
- ☒ hearing impaired
- ☒ hearing impairment aggravated
- ☒ hyperacusis
- ☒ hypoacusis
- ☒ presbycusis
- ☒ inner ear and VIIIth cranial nerve disorders
- ☒ middle ear disorders (exc congenital)
- ☒ miscellaneous ear disorders
- ☒ endocrine disorders
- ☒ eye disorders
- ☒ gastrointestinal disorders

Generate profile for this filter (This Filter has not been profiled)

Figure 13

Below are the top 200 correlated terms for your analysis on CANDESARTAN CILEXETIL. (Rank 95) View with ImageView

Correlated Terms					
[Rank]	[Score]	[Term 1]	[Category]	[Term 2]	[Category]
1	7708	Female	Sex	CANDESARTAN CILEXETIL	Target Drug
2	7691	Renal function analyses	Other Reaction	Renal failure and impairment	Other Reaction
3	7244	Paralysis (exc congenital and cranial nerve)	Other Reaction	Central nervous system haemorrhages and cerebrovascular accidents	Other Reaction
4	6901	HOS	Outcome	CANDESARTAN CILEXETIL	Target Drug
5	6888	TRIAMTERENE	Other Drug	DICLOFENAC SODIUM	Other Drug
6	6288	OTH	Outcome	CANDESARTAN CILEXETIL	Target Drug
7	5888	Sex Not Specified	Sex	Age Not Specified	Age
8	5773	VERAPAMIL	Other Drug	TRIAMTERENE	Other Drug
9	5765	HOS	Outcome	Female	Sex
10	5753	Male	Sex	CANDESARTAN CILEXETIL	Target Drug

0962136 090201

Figure 14

Correlation Details:
 Analyzed Drug: CANDESARTAN CILEXETIL
 Cases for term pair: Renal function analyses (Other Reaction) / Renal failure and impairment (Other Reaction)

Cases 1 to 18 of 18 cases

Case ID	Sex	Manufacturer Control Code	FDIA Report Receipt Date	Age	Drugs	Reactions	Serious
1 3263641	F	19990300088	1999-08-17	74	Atacand	Blood Creatinine Increased; Dialysis Nos; Renal Failure Aggravated	N
2 3198047	F	19990200143	1999-03-12	57	Acunetic, Atorvastatin, Atacand, Cefixime, Nitro-Dur, Terbasmin Expectorants	Blood Creatinine Increased; Blood Urea Increased; Hypotension NOS; Renal Failure Acute	Y
3 3171644	F	19981100002	1999-01-17	69	Xanax, Acetylsalicylic Acid, Welbutrin, Atacand, Arthroac, Digoxin, Levaquin, Claritin, Antivert, Pyridium, Zolof, Dyazide, Verapamil - Slow Release, Ambien	Abdominal Pain Nos; Blood Creatinine Increased; Blood Urea Increased; Coronary Artery Disease Nos; Haemoptysis; Heart Rate Increased; Hypertension Aggravated; Renal Failure Acute	N
4 3270258	F	19990400499	1999-05-26	75	Atacand, Hydrochlorothiazide	Antoventricular Block Second Degree; Blood Creatinine Increased; Blood Pressure Decreased; Electrocardiogram ST Segment Depression; Electrocardiogram U Wave Appearance; Electrolyte Imbalance; Hypochloremia; Hypokalemia; Hyponatremia; Loss Of Consciousness Nec; Renal Impairment Nos; Syncope	N

09581536-050201

Figure 15

Correlation Details						
Analyzed Drug: CANDESARTAN CILEXETIL						
Case for term pair: Renal function analyses (Other Reaction) / Renal failure and impairment (Other Reaction)						
1501	Case ID:	3198047				
1502	Sex:					
1503	Age:	57.0 years, 0.0 months				
1504	Reactions:	As Reported	Preferred Term	High Level Term	High Level Group Term	System Organ Class
		Blood Creatinine Increased	Blood Creatinine Increased	Renal function analyses	Renal and urinary tract investigations and urinalysis	Investigations
		Blood Urea Increased	Blood Urea Increased	Renal function analyses	Renal and urinary tract investigations and urinalysis	Investigations
		Hypotension NOS	Hypotension NOS	Hypotension	Decreased and non-specific blood pressure disorders and shock	Vascular disorders
		Renal Failure Acute	Renal Failure Acute	Renal failure and impairment	Renal disorders (except nephropathies)	Renal and urinary disorders
1505	Concomitant Drugs:	Name	Dose	Route	Suspect	Status
		Acute	TAB QD		Yes	
		Atorvastatin			No	
		Atacand	16 MG QD PO ORAL		Yes	
		Cefixime			No	
		Nitro-Dur			No	
		Terbacmin, Expectorante			No	
1506	Outcomes:	HOSPITALIZATION - INITIAL OR PROLONGED (H0) LIFE-THREATENING (LT)				
1507	Manufacturer Control Code:	0990200143				
1508	Manufacturer Date:	1990-03-5				
1509	Adverse Event Date:	1998-12-13				
1510	Report Type:	EXP				
1511	Report Source:	OTH				
1512	Case Source:	AERS				
1513	Narrative:					

TO2050-9857890

THE **WORLD'S** **LARGEST** **BOOKSTORE**

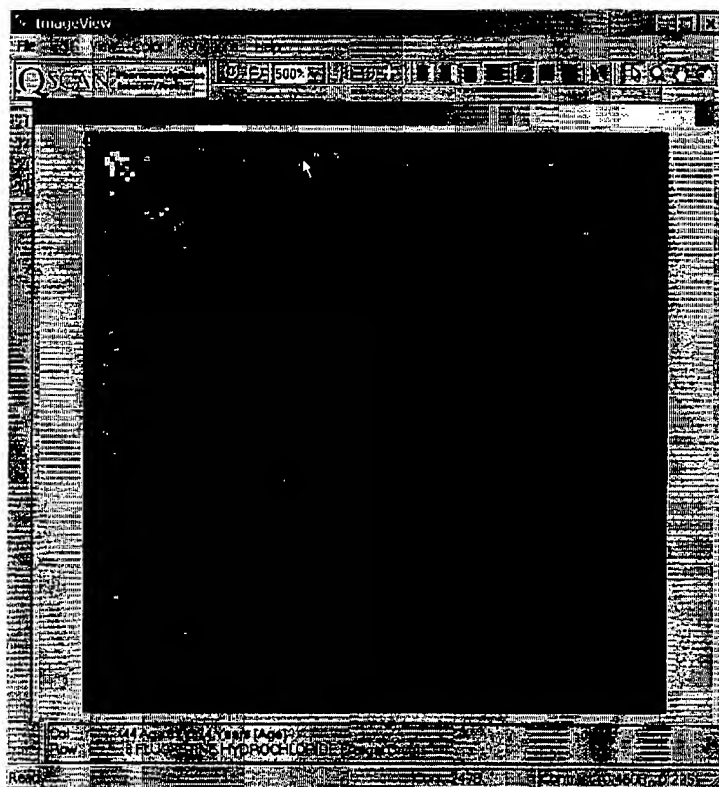
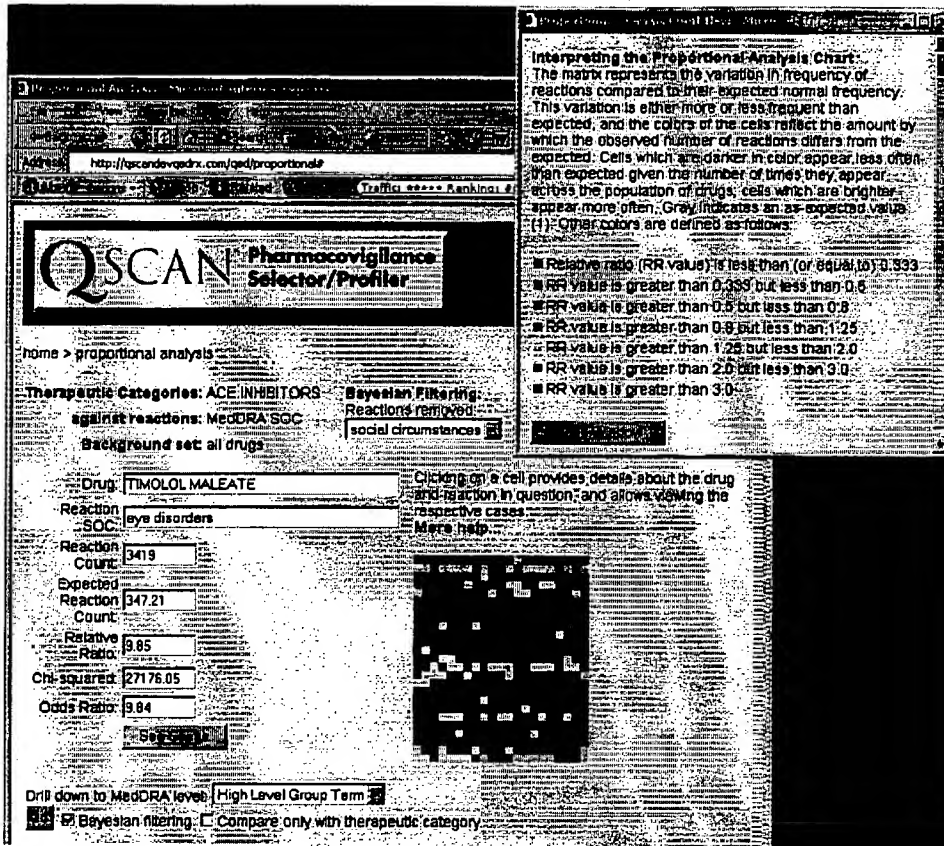


Figure 17



09681586 "05001

Figure 18

Proportional Analysis (ACGHIHIBITORS) vs. Reactions (SOCs) View by HLGs	
1800	Drug: AMLODIPINE BESYLATE
1801	Reaction: Surgical and medical procedures
1802	Reaction Count: 927
1803	Expected Reaction Count: 201.02
1804	Relative Ratio: 4.61

102050 " 98518960

Figure 19

550 entries for this analysis are displayed below:

Correlated Terms		1900	1901	1902	1903	1904
[Reaction]	[Drug]	[Count]	[Expected Count]	[Relative Ratio]		
1 6: Eye disorders	19: TIMOLOL MALEATE	3392	346.3	9.8		
2 24: Surgical and medical procedures	2: AMLODIPINE BESYLATE	1732	200.4	8.6		
3 14: Metabolism and nutrition disorders	1: AMILORIDE HYDROCHLORIDE	638	266.5	3.1		
4 24: Surgical and medical procedures	13: METHYLBOPA	37	15.6	2.4		
5 16: Neoplasms benign and malignant (including cysts and polyps)	17: RESERPINE	65	28.6	2.3		
6 4: Ear and labyrinth disorders	4: CANDESARTAN CILEXETIL	32	14.3	2.2		
7 24: Surgical and medical procedures	20: TRANDOLAPRIL	13	6	2.2		
8 14: Metabolism and nutrition disorders	18: SPIRONOLACTONE	1330	616.1	2.2		

102050 9851860

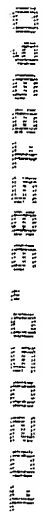


Figure 21

home > drug selector > drug profile > case list

Drug: BENAZEPRIL HYDROCHLORIDE

Reactions SOC: Included

Concomitant Drugs:

Demographics of:

Report Date of:

Discontinue:

Summary view... Cases 1 to 50 of 289 cases

6 pages

1: 61 101 151 201 251 2101 2102 2103 2104 2105 2106 2107

Case ID	Sex	Manufacturer Control Code	FAA Report (accept Date)	Age	Drugs	Reactions	Serious
1 3510123	F	200010174BGE	2000-05-1		Tylenol, Abutanol, Duragesic G Pm, Aspirin, Acetaminophen Ex Eib, Asteirin, Lotensin, Zyltad, Oxycodone, Benadryl, Premarin, Laxia, Mclz 25 Mg, Hydrocortisone, Immune Globulin Intravenous (Human), Gamimune N 10% - Placebo, Iodine, Xylocaine, Claritin, Glucophage, Methylprednisolone, Nasonex, Singulair, Pilozac, Oxygen, Paxil, Solumadrol Pack, Rezulin 200 Mg Am	Cardiac Murmur Nos, Dyspepsia, Dyspnea Nos, Oedema Lower Limb, Pain In Limb, Pruritus Nos, Physical Examination Nos Abnormal, Rhinorrhea, Tenderness Nos, Venous Thrombosis Deep Limb	Y
2 C01979033	F	67USA40861	1997-08-8		LOTENSIN	Hypertension NOS, Tachycardia	N
3 3204366	F	98061673	1999-03-26		Aspirin Coated, Lotensin, Neaspan	Asthenia, Dizziness (Exc Vertigo), Dyspepsia, Flushing, Pain Nos	Y
4 C01465473	F	833644001	1994-05-29		LOTENSIN	Nausea, Vasodilation	Y

102050 " 981360